UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/425,289	10/25/99	TONER J	

HM12/0725

ROYAL N. JR., VICE PRESIDENT
INTELLECTUAL PROPERTY DEPARTMENT
AMERSHAM PHARMACIA BIOTECH INC.
800 CENTENNIAL AVENUE, P.O. BOX 1327
PISCATAWAY NJ 08855-1327

EXAMINER	
HARTLEY,	

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 07/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary	Application No. 09/425,289	Applicant(s) TONER ET AL.	
	Examiner Michael G. Hartley	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6 and 8-40* is/are pending in the application.

4a) Of the above claim(s) *8-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

The amendment filed 7/9/2001 has been entered. Claims 1 and 7 have been canceled. New claims 38-40 have been added. Claims 2-6 have been amended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumiaki (JP 63255231), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 7/9/2001 have been fully considered but they are not persuasive.

Applicant asserts that in the methods disclosed by Sumiaki, the embolus agent includes an anti-neoplastic agent, which is not the case in the instant invention.

This is not found persuasive because it is noted that the instant claims use the term "comprising" to describe the embolism composition, which would not exclude the anti-neoplastic agent which is absorbed on the surface of the particles. While the claims use the terminology "consisting essentially of" in describing the particles, this use would not exclude the anti-neoplastic agent, which is absorbed onto the particles disclosed by Sumiaki for several reasons. First the anti-neoplastic agent is not part of the microparticles, but is absorbed onto the particles. Second, the phrase "consisting essentially of" only excludes ingredients that would affect the basic and novel characteristics of the product as defined in the claim. See *In re Gernero* (CCPA 1960) 412 F2d 276, 162 USPQ 221. This is not the case in the instant situation, since the inclusion of the anti-neoplastic agent would not effect the embolizing characteristic of the particles disclosed by Sumiaki. Also, the phrase "consisting essentially of" does not mean "consisting solely of," see *Ex parte Appeldorn* (POBA 1967) 159 USPQ 791. The phrase "consisting essentially of"

does not limit the claims so as to exclude other things when the specification clearly indicates other constituents may be present. *Ex parte Boukidis* (POBA 1966) 154 USPQ 144. The instant specification clearly states that "the particulate embolus generating agent also contains a cytotoxic agent" see page 14.

Applicant further asserts that the embolytic particles disclosed by Sumiaki do not include a diagnostically effective compound, rather the particles themselves are diagnostically effective.

This is not found persuasive because, "a non radioactive diagnostically effective compound," given its broadest reasonable interpretation, would mean any compound which is effective for providing diagnosis. Thus, since the particles disclosed by Sumiaki are diagnostically detectable, they inherently contain a (non-radioactive) diagnostically effective compound. For example, since the particles themselves are diagnostically detected, the particles must contain a compound which diagnostically effective.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuru (US Pat. 5,055,307), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 7/9/2001 have been fully considered but they are not persuasive.

Applicant asserts that Tsuru is directed to a method of drug delivery and not to a use of embolytic particles containing a contrast agent for imaging purposes.

This is not found persuasive because Tsuru clearly discloses that the particles are used in methods of embolus therapy, as set forth in the previous office action, see column 3, lines 27+. Since the particles have excellent imaging properties for X-ray and ultrasound imaging, such particles inherently contain a "diagnostically effective compound" as claimed. For example, the compounds used to make the particles disclosed by Tsuru are "diagnostically effective" when in particulate form.

Applicant further asserts that there is no contrast agent contained in the particles themselves (as disclosed by Tsuru), but that the particles are administered in a suspension of contrast agent.

This is not found persuasive because the particles themselves are capable of being diagnostically effective, thus contain a diagnostically effective compound. However, the use of the iodinated contrast agent disclosed in example 1 is within the scope of the instant claims. The particles disclosed by Tsuru are porous, see abstract and example 1. Thus, the solution of iodinated contrast agent when added to the porous particles would fill the pores and be a solution encapsulated in the particulate matrix as instantly claimed.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada (EP 470569), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 7/9/2001 have been fully considered but they are not persuasive.

Applicant asserts that the contrast agent is dispersed with the particles as opposed to being encapsulated in a matrix as claimed.

This is not found persuasive because when the porous particles disclosed by Okada are dispersed in a solution of contrast agent, the contrast agent would enter the pores and become encapsulated in a particulate matrix as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Sumiaki (JP 63255231) or Tsuru (US Pat. 5,055,307) or Okada (EP 470569) in view of Meeh (WO 95.27437), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 7/9/2001 have been fully considered but they are not persuasive.

Applicant asserts that this rejection falls since the primary references do not disclose the claimed method, as argued.

This is not found persuasive because the primary references do disclose a method that is encompassed by the claims for the reasons, as addressed above.

Response to Arguments

Applicant's arguments with respect to claims 2-6 and 38-40 have been considered but are moot in view of the following new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 38, the recitation of "A method of embolus therapy comprising a composition" is confusing because it appears to be grammatically incorrect. It appears to be missing an administration step.

Claim 4 recites the limitation "said reduced perfusion" in line 3. There is insufficient antecedent basis for this limitation in the claim.

In claim 5, the recitation that the particles "comprise" an insoluble phosphate salt" is confusing because it is not clear if the particles further comprise such a salt or if this phosphate salt is further defining the non-polymeric particulate matrix as set forth in the base claim (claim 38).

Claim 6 recites the limitation "said insoluble phosphate salt" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

The dependent claims fall therewith as being dependent on an indefinite claim.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Michael G. Hartley
Primary Examiner
Art Unit 1619

MH
July 24, 2001